

**Massachusetts Department of Public Health (MDPH)
Division of Epidemiology and Immunization**

Shingles Vaccine Information

On May 25, 2006, the Food and Drug Administration (FDA) licensed a shingles (herpes zoster) vaccine (Zostavax[®], Merck), for use in people 60 years of age and older.

Advisory Committee on Immunization Practices (ACIP) Recommendations

On October 25, 2006, the ACIP voted on recommendations for the use of a *single* dose of shingles vaccine. These provisional recommendations are for vaccination for all persons 60 years of age and older, including those who have previously had shingles, to prevent shingles and post-herpetic neuralgia. Persons with chronic medical conditions may be vaccinated unless a contraindication or precaution exists.

The ACIP provisional recommendations can be found at the Centers for Disease Control and Prevention (CDC) website <http://www.cdc.gov/nip/ACIP/default.htm>, but are not considered final until they are published in CDC's *Morbidity and Mortality Weekly Report (MMWR)*. When the final recommendations are published they will also be accessible on the CDC website.

Shingles

Shingles is caused by reactivation of the varicella zoster virus, which lies dormant in the nerve cells of a person who has had chickenpox (or received varicella vaccine). Years or decades later, the virus may reactivate and cause shingles. The risk of shingles is greatest in the elderly and those who are immunocompromised. Risk increases with age.

Shingles Vaccine

Shingles vaccine contains the same virus strain (Oka/Merck) as varicella vaccine, but is 14 times more potent. The vaccine is given as a single, 0.65 mL dose, administered subcutaneously.

In clinical trials, those who received vaccine had about 50% fewer cases of shingles, less severe disease and 66% less postherpetic neuralgia than those who received placebo. For more information on the efficacy and safety of shingles vaccine, including contraindications and precautions to the use of shingles vaccine, please see the Zostavax[®] package insert:

http://www.merck.com/product/usa/pi_circulars/z/zostavax/zostavax_pi.pdf.

Storage and Handling of Shingles Vaccine

Shingles vaccine, like varicella vaccine, has very specific storage and handling requirements:

- Shingles vaccine must be kept frozen ($\leq -15^{\circ}\text{C}$ or $\leq +5^{\circ}\text{F}$) at all times. Diluent should be stored separately at room temperature (20-25°C, 68-77°F) or in the refrigerator (2-8°C, 36-46°F).
- A frost-free freezer with a separate, insulated door which maintains a freezing temperature ($\leq -15^{\circ}\text{C}$ or $\leq +5^{\circ}\text{F}$) should be used to store shingles vaccine until it is reconstituted.
- Dorm style refrigerators with a freezer compartment are **not** acceptable for vaccine storage.
- Reconstitute shingles vaccine immediately after it is removed from the freezer.
- Shingles vaccine must be used within 30 minutes of reconstitution or discarded.
- Reconstituted vaccine should not be frozen.

It is important to ensure that you have the equipment to store vaccines and medications which require refrigeration or freezing appropriately. In addition to shingles vaccine, vaccines for adults, including human papillomavirus (HPV) and tetanus, diphtheria and acellular pertussis (Tdap) vaccines also have specific storage requirements, but at refrigerator temperature (2-8°C or 36-46°F). While stand alone

refrigerators and freezers are best, it is permissible to have a household style refrigerator/freezer unit as long as the freezer has a separate, insulated door and maintains a temperature of $\leq -15^{\circ}\text{C}$ or $\leq +5^{\circ}\text{F}$.

Please be aware that dorm style refrigerators with a freezer compartment are **not** acceptable for storage of any vaccines. It is worth the investment to ensure that your patients receive vaccine which hasn't been compromised by inadequate storage conditions, and to guard against excess costs from loss of vaccines due to inappropriate storage.

Vaccine Information Statements

An interim vaccine information statement (VIS) for shingles vaccine was issued on September 11, 2006 and is available at: <http://www.immunize.org/vis>. A *final* VIS will be published with a new date and a copy will be available at the above website.

Reporting of Adverse Events after Vaccination

It is important for all clinically significant adverse events to be reported to the Vaccine Adverse Event Reporting System (VAERS), even if a causal relationship to vaccination is uncertain. VAERS reporting forms and information are available electronically at: <http://vaers.hhs.gov> or by calling (800) 822-7967. Providers are encouraged to report electronically at: <https://secure.vaers.org/VaersDataEntryintro.htm>

Vaccine Availability and Ordering

MDPH is not supplying shingles vaccine. Physicians will have to purchase shingles vaccine for their patients. Zostavax[®] can be ordered from a vaccine distributor, or directly from the vaccine manufacturer, Merck (<http://www.merckvaccines.com> or 1-800-637-2590). The current procedural terminology (CPT) code for shingles vaccine is 90736; this code should be used for reimbursement. Shingles vaccine will be reimbursed for some Medicare beneficiaries through Medicare Part D (unlike influenza and pneumococcal polysaccharide vaccine, which are covered under Medicare Part B). Coverage for shingles vaccine depends on the Part D plan, and details about coverage and various mechanisms for reimbursement are evolving. Beneficiaries can contact their plan for more information regarding coverage and how the vaccine can be administered.

For a list of vaccines currently supplied by MDPH, please see the documents *Childhood Vaccine Availability Table* and *Adult Vaccine Availability Table* on the MDPH website:

<http://www.mass.gov/dph/cdc/epii/imm/imm.htm#management>.

Resources

For additional information regarding shingles and shingles vaccine, consider the following resources:

- <http://www.cdc.gov/nip/vaccine/zoster/default.htm>
- <http://www.zostavax.com/>
- <http://www.fda.gov/cber/products/zosmer052506qa.htm>
- <http://www.immunize.org/vis/shingles.pdf> (vaccine information statement for shingles vaccine)

References

ACIP Provisional Recommendations for the Use of Zoster Vaccine. Accessed January 22, 2007. Available at: http://www.cdc.gov/nip/recs/provisional_rec/zoster-11-20-06.pdf

Adult Immunization 2006. Satellite Broadcast, December 7, 2006. Zoster Vaccine Segment slides. Accessed January 22, 2007. Available at: http://www.cdc.gov/nip/ed/AdultUpdate2006/adultim06_zoster.ppt

CDC. Herpes Zoster Vaccine (Shingles) Q&A. Available at: <http://www.cdc.gov/nip/vaccine/zoster/faqs-vacc-zoster.htm>. Accessed on: 1/23/2007.

Zostavax[®] package insert. Accessed January 22, 2007. Available at: http://www.merck.com/product/usa/pi_circulars/z/zostavax/zostavax_pi.pdf